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Please type a plus sign (+) inside this box → PTO/SB/05 (4/98)
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Patent and Trademark Office: U S DEPARTMENT OF COMMERCE

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No. 70006780-0008

First Inventor or Application Identifier Boris V. Smolyarov

Title See 1 in Addendum

Express Mail Label No. EL654784033US

S-1
S-2
S-3
S-4**APPLICATION ELEMENTS**

See MPEP chapter 600 concerning utility patent application contents.

1. * Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. Specification [Total Pages 20]
(preferred arrangement set forth below)
 - Descriptive title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. Drawing(s) (35 U.S.C. 113) [Total Sheets 5]
4. Oath or Declaration [Total Pages]
 a. Newly executed (original or copy)
 b. Copy from a prior application (37 C.F.R. § 1.63(d))
 i. DELETION OF INVENTOR(S)
 Signed statement attached deleting
 inventor(s) named in the prior application,
 see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

* NOTE FOR ITEMS 1 & 13 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

5. Microfiche Computer Program (Appendix)
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
 - a. Computer Readable Copy
 - b. Paper Copy (identical to computer copy)
 - c. Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. Assignment Papers (cover sheet & document(s))
8. 37 C.F.R. § 3.73(b) Statement Power of
(when there is an assignee) Attorney
9. English Translation Document (if applicable)
10. Information Disclosure Statement (IDS)/PTO-1449 Copies of IDS
Statement (IDS)/PTO-1449 Citations
11. Preliminary Amendment
12. Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. * Small Entity Statement(s) Statement filed in prior application
(PTO/SB/09-12) Status still proper and desired
14. Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. Other: See 2 in Addendum.....

16. If a CONTINUATING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment.

Continuation Divisional Continuation-in-part (CIP) of prior application No. /

Prior application information: Examiner _____

Group / Art Unit: _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

<input type="checkbox"/> Customer Number or Bar Code Label / (Insert Customer No. or Attach bar code label here)		or <input checked="" type="checkbox"/> Correspondence address below		
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Name (Print/Type)	Joseph A. Mahoney	Registration No. (Attorney/Agent)	38,956
Signature			

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S-2
S-3
S-4

11/21/00

**Attachment to PTO/SB/05 (4/98) Utility Patent Application
Transmittal**

1. SAFETY MECHANISM TO PREVENT ACCIDENTAL PATIENT INJECTION AND METHODS OF SAME
2. - Unexecuted Oath and POA
- Applicant hereby claims small entity status

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FEE TRANSMITTAL

for FY 2000

Patent fees are subject to annual revision

Small Entity payments must be supported by a small entity statement, otherwise large entity fees must be paid. See Forms PTO/SB/09-12
See 37 C.F.R. §§ 1.27 and 1.28.

TOTAL AMOUNT OF PAYMENT (\$472.00)

Complete if Known

Application Number	
Filing Date	November 22, 2000
First Named Inventor	Boris V. Smolyarov
Examiner Name	
Group / Art Unit	
Attorney Docket No.	70006780-0008

METHOD OF PAYMENT (check one)

1. The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit Account Number [redacted]

Deposit Account Name [redacted]

 Charge Any Additional Fee Required
Under 37 CFR §§ 1.16 and 1.172. Payment Enclosed: Check Money Order Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
101 690	201 345	Utility filing fee	355.00
106 310	206 155	Design filing fee	
107 480	207 240	Plant filing fee	
108 690	208 345	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$355.00)

2. EXTRA CLAIM FEES

Total Claims	Extra Claims	Fee from below	Fee Paid
33	-20** = 13	x 9	= 117
Independent Claims 3	- 3** = 0	x 40	= 0
Multiple Dependent			= 0

**or number previously paid, if greater; For Reissues, see below

Large Entity Small Entity

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
103 18	203 9	Claims in excess of 20
102 78	202 39	Independent claims in excess of 3
104 260	204 130	Multiple dependent claim, if not paid
109 78	209 39	** Reissue independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$117.00)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	0.00
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	0.00
139 130	139 130	Non-English specification	0.00
147 2,520	147 2,520	For filing a request for reexamination	0.00
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	0.00
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	0.00
115 110	215 55	Extension for reply within first month	0.00
116 380	216 190	Extension for reply within second month	0.00
117 870	217 435	Extension for reply within third month	0.00
118 1,360	218 680	Extension for reply within fourth month	0.00
128 1,850	228 925	Extension for reply within fifth month	0.00
119 300	219 150	Notice of Appeal	0.00
120 300	220 150	Filing a brief in support of an appeal	0.00
121 260	221 130	Request for oral hearing	0.00
138 1,510	138 1,510	Petition to institute a public use proceeding	0.00
140 110	240 55	Petition to revive - unavoidable	0.00
141 1,210	241 605	Petition to revive - unintentional	0.00
142 1,210	242 605	Utility issue fee (or reissue)	0.00
143 430	243 215	Design issue fee	0.00
144 580	244 290	Plant issue fee	0.00
122 130	122 130	Petitions to the Commissioner	0.00
123 50	123 50	Petitions related to provisional applications	0.00
126 240	126 240	Submission of Information Disclosure Stmt	0.00
581 40	581 40	Recording each patent assignment per property (times number of properties)	0.00
146 690	246 345	Filing a submission after final rejection (37 CFR § 1.129(a))	0.00
149 690	249 345	For each additional invention to be examined (37 CFR § 1.129(b))	0.00
Other fee (specify)			0.00
Other fee (specify)			0.00

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$0.00)

SUBMITTED BY

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Signature	[Signature]			Date	21 Nov. 2000

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UNITED STATES PATENT APPLICATION FOR

Safety Mechanism To Prevent Accidental Patient Injection and Methods of Same

Inventors:

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Victor T. Rogatchev

Victor N. Katov

Nathaniel Leon

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Express Fair mailing label number:
Opellen Hooper

Safety Mechanism To Prevent Accidental Patient Injection and Methods of Same**Cross Reference of Related Applications:**

5 This application claims priority to, and benefit from, US Patent Applications Serial Nos. 09/685,499, filed 10 Oct. 2000; 09/685,633, filed 10 Oct. 2000; and Russian Patent Application No. 99124268, filed 23 Nov. 1999, which is now Russian Patent No. 2152228; the disclosures of which are entirely incorporated by reference herein to the extent permissible by law.

Technical Field of the Invention:

The invention relates to a medical injection assembly in which the assembly is adapted to reduce the risk of accidental injection of a patient.

Background of the Invention:

20 The most effective measure to prevent many diseases is the mass immunization with vaccines. Since medical science has come to understand the principles of viral theory and its importance to the transmission of diseases, the need to break the viral or bacterial transmission chain from host to host has become well-established. There are wide varieties of methodologies accepted by medical science to break the chain depending on the requirements of the situation. The most stringent protocols include: sterilization, disinfection, and sanitization utilizing heat chemicals and/or ionizing radiation.

Barriers are another common protocol and can be as simple as establishing an imaginary boundary where one side of the boundary is kept clean and the other is defined as contaminated. Any object being transferred from the clean to the contaminated side of the boundary is not returned to the clean side without being disinfected, sanitized, or sterilized. A typical example of this type of protocol is within the medical surgical fields.

The surface of the operating table is defined as the boundary. Any item that is dropped below the surface of the operating table is immediately defined as contaminated. This includes surgical implements or the surgeon's hands.

With needle injection devices there are two common protocols both of which start from the premise that a used syringe is, by definition, contaminated. The first, which is commonly used in dentistry, uses syringes and sometimes needles that are sterilized after each use. The second is more commonly used in general medicine in the U.S. and other developed countries. This is the disposable syringe and needle assembly. Because of the low cost of production typically - less than \$0.10 per syringe assembly – this protocol is well-accepted.

Jet injector systems on the other hand continue to be characterized by relatively high cost per injection (\$1.00 or more) when the syringe portion of the injector is discarded with each use. Additionally, there is the challenge in developing countries where lack of understanding of viral theory and/or a general hoarding mentality discourages following generally accepted protocols within all aspects of health and hygiene. With the identification of blood-borne pathogens like HIV, Hepatitis B, Hepatitis C and others, the need to follow proper protocols becomes more critical.

In the past, jet injectors such as Ped-O-Jet®, Ammo-Jet®, and similar mass campaign jet injectors were brought to health care systems. Such injectors had no provision for preventing the transfer of blood-borne pathogens except through the complicated disassembly and disinfecting process. In mass immunization campaigns these types of injector systems fell out of favor starting in the mid and late 1980's when it was determined that bodily fluids are easily transmitted from one patient to another.

To eliminate the possible transmission of blood-borne pathogens between individuals, disposable or partially disposable jet injector systems were developed. Bio-Jet®, J-Tip®, and others characterize this type of jet injector. General acceptance of these units is limited by relatively high direct costs, even in developed countries like the United States. The standard paradigm of breaking the contamination transmission chain has been addressed by either syringe disposal or designing the syringe so it can easily be decontaminated. Currently, there exists a steadily growing danger of the epidemic diseases (AIDS, hepatitis, tuberculosis and other viral diseases transferred through blood) being transmitted between individuals through the use of needleless injectors.

The traditional needleless injectors comprise the basic design, a housing with an inner power unit, a medication unit, and a nozzle. The function of the power unit pumps the medication into an under-plunger cavity of the medication unit chamber and to expel the medication through the nozzle.

At the initial stage of needleless injector development, when no check valves were used as a control for the functioning of the medication chamber, a method to prevent foreign particles from entering the injector nozzle was to use a sealed nozzle cap. Such

cap was limited by the filling of the medication chamber with medication and could not guarantee contamination prevention.

Another approach to the contamination prevention problem has been the use of a disposable, low cost, one-shot nozzle assembly for jet injectors. The nozzle assembly 5 comprises a two-piece molded device incorporating a generally cylindrical nozzle body having a central longitudinal bore of a predefined diameter, extending from a proximal end of the nozzle towards its distal end, terminating in a conical portion of the nozzle. A very small diameter jet-forming bore is formed at the apex of the conical portion of the bore in general. The disadvantage of this device is its lower efficiency (i.e., low vaccination rate) because of poor flow due to the conical design. Moreover, a plastic nozzle element also increases the vaccination cost.

A typical jet injector design has additional drawbacks. Even in the practice of using a protective cap, there is a possibility of infection transfer from one person to another by means of fluids (blood, lymph, medication) reflected from the skin surface during injection ("back splash") that may get on the nozzle and be transferred from one patient to the next. The protective cap can be a one-shot cap, including the injection nozzle. A purpose of this device is to prevent the multiple use of a cap with a nozzle. This is achieved through the removal, replacement, and/or destruction of the cap at the later stage of the injection. However, cross-contamination continues to be problematic 15 because in the injection stage, the contaminated matter can be transferred through the nozzle to inside the injector such as, for example, into the cavity and be transmitted to a new patient through a new cap and nozzle.

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With all the known devices, there is no guarantee that the minimum safety requirements for cross-contamination prevention, as recently introduced (Glenn Austin et al., *Gross Contamination Testing of Vaccine Jet Injectors, A Preliminary Report*, PATH, Seattle, WA, 98109), will be achieved. Other studies indicate a very dangerous situation.

5 For example, Russian and Brazilian studies have shown unfavorable data in up to 1.0% of the subjects studied – a level of risk far too great to ignore.

When jet injectors were introduced in the 1940's, they were popular for needle phobic patients or small veined patients. Improvements permitted jet injectors to administer hundreds of millions of vaccinations that saved countless lives. However, when the discovery of pathogen transfer occurred, jet injectors fell out of favor to such an extent that the WHO and the U.S. Department of Defense no longer recommended jet injector .

For example, in the mid-1980's an outbreak of Hepatitis B was caused by use of one high workload injector in a weight loss clinic. See, Canter et al., An Outbreak of 15 Hepatitis B Associated With Jet Injections In A Weight Loss Clinic, Arch. Intern. Med., 150:1923-1927 (1990).

Present parenteral injection technology has recently been deemed by the World Health Organization (WHO) to be incompatible with their requirements for the planned Global Programme of Vaccination and Immunization (GPIV) initiatives. It is estimated that 20 6 additional parenteral vaccines will be recommended for childhood vaccination by the year 2005, requiring a total of 3.6 billion immunization injections per year. The total number of parenteral injections, including injected drugs as well as vaccines, will be roughly ten times this number. This is in addition to the hundreds of millions needed in

military induction centers, epidemic situations, worldwide immunizations, and veterinary uses. Major health care providers such as UNICEF, the WHO and CDC have recently confirmed that a radical new technology is required that can be used by personnel with minimal training and that is safer, more convenient, and more comfortable than the syringe and needle. (Jodar L., Aguado T., Lloyd J. and Lambert P-H,(1998) Revolutionizing Immunizations Gen. Eng. News 18, p. 6.)

In other words, what used to be a continent wide life saver, became an undesirable product. The present invention solves problems associated with pathogen transfer and solves many problems associated with the high costs of disposable units.

Coupled with this was that accidental discharge of the medication sometimes occurred. Premature injection could result in an incomplete injection or an injection in the improper situs.

Accordingly, there is a need in the art of needleless injection devices to solve the problem of cross-contamination during mass vaccinations. More particularly, there is a need for a protector designed for the nozzle head of needleless injectors, which halts "back splash" contamination, and which is low enough in cost to ensure its practical application as a disposable unit even for mass vaccinations. There is also a need to ensure that the incidence of premature discharge is reduced or eliminated.

Summary of the Invention:

The foregoing problems are solved and a technical advance is achieved by the present invention. Disclosed is medical injection assembly in which the assembly is

adapted to reduce the risk of accidental injection of a patient. Manners of doing so include permitting the injection assembly to fire but blocking the medication stream or stopping the injection assembly from firing in the first place.

5 **Brief Description of the Drawings:**

FIG. 1 is one simple embodiment of the invention showing the injector and cap.

FIG. 2 is another embodiment of the invention showing one cap embodiment.

FIG. 3 is another embodiment of the invention showing one blocking mechanism.

FIG. 4 is another embodiment of the invention showing one blocking mechanism.

FIG. 5 is another embodiment of the invention showing one blocking mechanism.

FIG. 6 is another aspect of the invention of FIG. 5.

FIG. 7 is another embodiment of the invention showing one blocking mechanism.

FIG. 8 is another embodiment showing the proximal end of the device.

FIG. 9 is another embodiment showing an orifice shield.

FIG. 10 is the embodiment of FIG. 9 in operation.

10 **Detailed Description of the Invention:**

FIG. 1 shows an embodiment of the invention. Disclosed is a medical device injection assembly 10. The injection assembly 10 further includes an injector assembly proximal end 12, an injector assembly distal end 14, and a distal end orifice 16. For the purposes of discussion, the terms distal and proximal are used to denote non-exclusive locations. The term “proximal” is used generally to describe the area normally closest to the physician or user. The term “distal” is used generally to describe the area close to the

patient or close to the end where the medication exits the device. The medication is dispensed via an injection piston 18 located generally within the injector lumen 20. Medication is pushed out by the injector piston 18 and the injector head 22. As the medication flows, it passes through the cap 24, by passing through the cap proximal face 28 and through the cap distal face 26. The cap distal face 26 is the face that generally faces the patient's skin 30.

FIG. 2 demonstrates the cap. Although one configuration of the cap is shown, it should be understood that the cap may be configured in the many ways shown in US Patent Application Serial No. 09/685,499, the disclosure of which is expressly incorporated by reference herein. The cap 24 includes a cap distal face 26 and a cap proximal face 28. The cap 24 also includes a protective layer such as a film 32. The film 32 may comprise comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof. While the film 32 is shown sandwiched between a first component 34 and a second component 36, it is understood that the film 32 may be in other locations. The film 32 generally covers the cap orifice 38. Therefore, the various placements, configurations, or numbers of films present that permit the covering of the cap orifice 38 is contemplated. The cap orifice 38 is configured so that it is coincident with the injector lumen 20 so that medication flowing out will generally travel through the film 32 and through the cap orifice 38 with minimal resistance.

FIG. 3 demonstrates one embodiment of the invention. Shown is an injection prevention component 40 generally, but not exclusively, located distal to the distal end orifice 16. In other embodiments, the injection prevention component may be proximal to part of the cap distal face 26. In one embodiment, the injection prevention component 40

may comprise an orifice shield 42, which generally covers or blocks (either partially or completely) the distal end orifice 16. One non-exclusive purpose of the orifice shield 42 is to interrupt the medication stream flow from the injector. It may do so by either blocking the entire stream path or part thereof. To facilitate the blocking or covering, the orifice shield 42 may be adapted to have a relatively flat face 44 or flat surface to maximize interruption or deflection. The injection prevention component may be attached to the injector assembly 10 via an injection prevention component attachment 46, which may include screws, adhesive, pins, slides, male-female receptacles, welds, bonds, bolts, or other well known mechanisms for attaching pieces together. The attachment and component may be anywhere along the injector.

The device 10 may also be fabricated as an integral piece or as separate pieces with the attachment 46. Thus, in the embodiment shown, since the cap 24 is not in place, the prevention component 40 extends out and blocks the path of the injector lumen 20. Thus, medication that sprays or is shot out, will generally impact the component 40 and prevent the accidental injection into the patient. Even if there is only partial blockage of the stream, then injection will likely not occur because the remaining stream may not have the required penetration velocity. Accordingly, the component 40 may be configured or adapted in such a way to be disposed distal to the distal end orifice 16, proximal to the cap proximal face 28, or proximal to part of the cap distal face 26.

FIG. 4 is another embodiment of the invention. Shown is the prevention component 40 moved out of the way by the cap 24. As the cap 24 moves into position, the cap pushes against the prevention component 40 so that it is no longer blocking the distal end orifice 16. Since the cap 24 is removable, the assembly 10 may also include a means 48 for biasing the cap. The mechanisms for biasing also are described in US Patent

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Application Serial No. 09/685,633, the disclosure of which is expressly incorporated by reference herein. The assembly 10 may also be configured to provide for an injection prevention component recess 50, in which the prevention component 40 may reside when the cap is put on. In this regard, the prevention component 40 may be neatly tucked in the recess 50. The prevention component 40 may also be adapted in such a way that it is totally out of the way of the distal end orifice 16 only when the cap 24 is firmly in place.

5 Thus, as the cap proximal face 28 begins contacting the prevention component 40, the component 40 will begin to move out of the way of the distal end orifice 16. Thus, the component 40 can still block until the cap is completely on and in place. Once the cap is ejected off, the component 40 moves back into blocking position. Thus, the component may also include a leaf spring or other resilient/elastic material that can “spring” back into place when unrestrained.

FIGs. 5 and 6 demonstrate yet another embodiment of the invention. Shown is the injection prevention component 40 shown as a prevention piston 52, which is partially disposed within the recess 50. The prevention piston 52 includes a piston head 54 detachably attached to a lock pin 56. The lock pin 56 is adapted to move within an injector piston recess 58. When the lock pin 56 is in the recess 58, the injector piston 18 cannot move. Also included is a biasing means such as a prevention piston return means 60, which may include a spring, deformable material (such as rubber or plastic), screw, or 20 the like. One purpose of the return means 60 is to move the prevention piston 52 back out and thus drop the lock pin 56, and accordingly, any means to bias the prevention piston 52 is contemplated, included those means for biasing the cap described in US Patent

It should be noted that any means for biasing can also include those means known in the art and can further include, but is not limited to, pistons, gears, rods, springs, worm gears, screws, deformable materials, electromagnets, optical components, and jacks. The means for biasing may also include various driving mechanisms, such as pneumatics, hydraulics, or manual drives. In addition, the means for biasing may also include phase change materials or other shape memory materials, such as those materials that change size or shape due to temperature application. One such material is Nitinol, which allows for size or shape transformation in its austenite and martensite states. Accordingly, the means for biasing is meant to include not only the structures described herein, but also, any acts or materials described herein, and also include any equivalent structures, equivalent acts, or equivalent materials; or structural equivalents, act equivalents, or material equivalents, to those described herein.

As shown in FIGs. 5 and 6, when the cap 24 approaches the distal end, it engages the prevention piston 52 and begins moving it inwards, thus compressing or deforming the return means 60. The lock pin 60, which was supported by the piston head 54, no longer has support and falls onto the piston 52 and thereby out of the injector piston recess 58.

Although not shown, the device 10 may be adapted to include a lock pin 56 that protrudes into the injector lumen 20 such that the lock pin 56 may engage the injector head 22, or be disposed distal to the injector head 22. Thus, the lock pin 56 need not solely enter the piston recess 58, but may interact with the piston 18 (or piston drive or release) in any fashion to keep it from moving forward, or otherwise interfere with the forward motion. Another embodiment of the invention may also include the orifice shield 42 as

described above to be used in conjunction with the prevention piston assembly shown anywhere herein.

FIG. 7 shows yet another embodiment of the invention. Shown is the injector assembly proximal end 12. In this embodiment, shown is the injector piston 18 and the injector piston biasing means 70. As described throughout, the means for biasing can also include those means known in the art and can further include, but is not limited to, pistons, gears, rods, springs, worm gears, screws, deformable materials, electromagnets, optical components, and jacks. The means for biasing may also include various driving mechanisms, such as pneumatics, hydraulics, or manual drives. In addition, the means for biasing may also include phase change materials or other shape memory materials, such as those materials that change size or shape due to temperature application. One such material is Nitinol, which allows for size or shape transformation in its austenite and martensite states. Accordingly, the means for biasing is meant to include not only the structures described herein, but also, any acts or materials described herein, and also include any equivalent structures, equivalent acts, or equivalent materials; or structural equivalents, act equivalents, or material equivalents, to those described herein.

In operation, as the prevention piston 52 is pushed in the direction from distal to proximal (the direction arrow X), then the piston 52 impacts against an injection prevention component 40, such as a latch 72. Latch 72 is adapted to interfere with the means for biasing the injection piston 74, which as described herein may include any biasing means above. In this regard, as the latch 72 engages or interferes with the means 74, it prevents the means from biasing the injection piston 18. As the cap 24 is placed on, it pushes the prevention piston 52 along, which impacts against the latch 72 and pushes the

latch 72 into a latch recess 76. Associated with the latch recess 76 and the latch 72 is a means 78 for biasing the latch 72 back up into the interference position. The means 78 may also include a small wad of rubber or a spring that pushes the latch 72 back into the injector lumen 20.

5 In addition, the injection prevention component 40 may also be adapted to work in conjunction with orifice shields and/or prevention pistons as described herein. Moreover, the prevention component 40 may be adapted to work in conjunction with pneumatically driven locking means, as described in the contemporaneously filed US Patent Application, (serial number unknown to be inserted later), entitled Injector Assembly with Driving Means and Locking Means, naming the following inventors, Boris V. Smolyarov and Victor T. Rogatchev, filed on (herewith) bearing attorney docket number 70006780-0007; the disclosure of which is expressly incorporated by reference herein. In that disclosure, a mechanism including rollers, retainers, annular grooves, and ball locks are disclosed.

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FIGs. 9 and 10, show another embodiment of the invention in which the orifice shield 42 interacts with a contained compression means 81, such as compression spring 81. The shield 42 pivots along an axle 80. In FIG. 9, when there is no cap pushing against the shield 42, the spring 81 is uncompressed and thereby pushes shield 42 in the way of the orifice. As the cap is put on, the shield 42 moves out of the way and compresses spring 81. As with any embodiment, the device may be adapted to hide the shield 42 away 15 into a recess or otherwise out of the way.

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In yet another embodiment of the invention, the invention may also comprise the various steps of operation. For example, also disclosed is a method of preventing the

accidental injection of medication into a patient and reducing the risks of cross contamination during injections, comprising the steps of:

- (a) loading a cap onto a distal end of an injector;
- (b) disengaging a locking mechanism to permit a stream of medication to exit the injector;
- (c) removing the cap after injection; and
- (d) engaging the locking mechanism to prevent a discharge of the medication.

Other steps parallel the steps described herein and the person of ordinary skill in the art would understand how to adapt the mechanism to further perform other steps. Thus, one embodiment of the invention may also include the process of adapting the device to include safety mechanisms as described herein.

It should be understood that the foregoing relates only to a limited number of embodiments that have been provided for illustration purposes only. It is intended that the scope of invention is defined by the appended claims and that modifications to the embodiments above may be made that do not depart from the scope of the claims.

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Claims:

We claim,

1. An injector assembly having a proximal end and a distal end, the distal end having a
5 distal end orifice, an injection piston located generally within an injector lumen,
comprising:
 - (a) a cap generally distal to the distal end orifice, the cap further including a cap distal face and a cap proximal face; and
 - (b) an injection prevention component disposed generally proximal to the cap distal face.
 - 10 2. The injector assembly of claim 1, wherein the cap further includes a cap orifice extending therethrough, the cap orifice also being coincident with the injector lumen.
 3. The injector assembly of claim 2, wherein the cap further includes a film disposed over the cap orifice.
 - 15 4. The injector assembly of claim 3, wherein the film comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof.
 5. The injector assembly of claim 2, wherein the injection prevention component further includes at least one of an orifice shield, a piston, and a latch.
 - 20 6. The injector assembly of claim 5, wherein the cap further includes a film disposed over the cap orifice.
 7. The injector assembly of claim 6, wherein the film comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof.

8. The injector assembly of claim 6, wherein the orifice shield is disposed generally distal to the distal end orifice.
9. The injector assembly of claim 6, wherein the orifice shield is disposed generally proximal to the cap proximal face.
- 5 10. The injector assembly of claim 6, wherein the orifice shield includes a generally flat surface adapted to partially or completely cover the distal end orifice.
11. The injector assembly of claim 6, wherein the orifice shield includes a generally flat surface adapted to block the distal end orifice.
12. The injector assembly of claim 6, wherein the orifice shield comprises a leaf spring.
- 10 13. The injector assembly of claim 6, wherein the orifice shield is detachably attached to a first side of the injector assembly.
14. The injector assembly of claim 6, wherein the orifice shield is adapted to cover the distal end orifice when the cap proximal face partially contacts the orifice shield.
15. The injector assembly of 14, wherein the orifice shield comprises a leaf spring.
- 15 16. The injector assembly of claim 15, wherein the orifice shield includes a generally flat surface adapted to generally block the distal end orifice.
17. The injector assembly of claim 6, wherein the piston further includes a lock pin.
18. The injector assembly of claim 17, wherein the lock pin protrudes into the injector lumen.
- 20 19. The injector assembly of claim 17, wherein the lock pin is adapted to interfere with the injection piston.
20. The injector assembly of claim 17, wherein the injection piston further comprises an injection piston recess adapted to detachably attach with the lock pin.

21. The injector assembly of claim 17, wherein the piston further comprises a rod disposed between the cap proximal face and the lock pin.
22. The injector assembly of claim 21, wherein the prevention component further comprises an orifice shield disposed distal to the distal end orifice.
- 5 23. The injector assembly of claim 21, wherein the film comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof.
24. The injector assembly of claim 6, wherein the latch is disposed at a proximal end of the injector lumen.
- 10 25. The injector assembly of claim 2, wherein the latch is adapted to disengageably engage with a proximal end of the injection piston.
26. The injector assembly of claim 25, wherein a rod is disposed between the cap proximal face and the injector lumen proximal end.
- 15 27. The injector assembly of claim 25, wherein the cap protective film comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof.
28. An injector assembly having a proximal end and a distal end, the distal end having a distal end orifice, an injection piston located generally within an injection lumen, comprising:
- 20 (a) a cap generally distal to the distal end orifice, the cap further including a cap distal face and a cap proximal face; and
- (b) a means for preventing the injection piston from moving from a locked position to a discharged position.

29. The injector assembly of claim 28, wherein the means for preventing the injection piston from moving includes at least one of an orifice shield, a piston lock, and a latch.
30. The injector assembly of claim 29, wherein a film is disposed over a cap orifice.
31. The injector assembly of claim 30, wherein the film comprises at least one of a plastic, rubber, polymer, polyethylene, polytetrafluoroethylene, polyurethane, polyolefin, polypropylene, and polysulfone material; or combination thereof.
- 5 32. The injector assembly of claim 31, wherein the cap proximal face is disconnectedly connected to the means for preventing the injection piston from moving.
33. A method of preventing the accidental injection of medication into a patient and reducing the risks of cross contamination during injections, comprising the steps of:
- 10 (a) loading a cap onto a distal end of an injector;
- (b) disengaging a locking mechanism to permit a stream of medication to exit the injector;
- (c) removing the cap after injection; and
- 15 (d) engaging the locking mechanism to prevent a discharge of the medication.

Abstract

Disclosed is a medical injection assembly in which the assembly is adapted to
reduce the risk of accidental injection of a patient and prevent cross contamination of
patients or injectors.

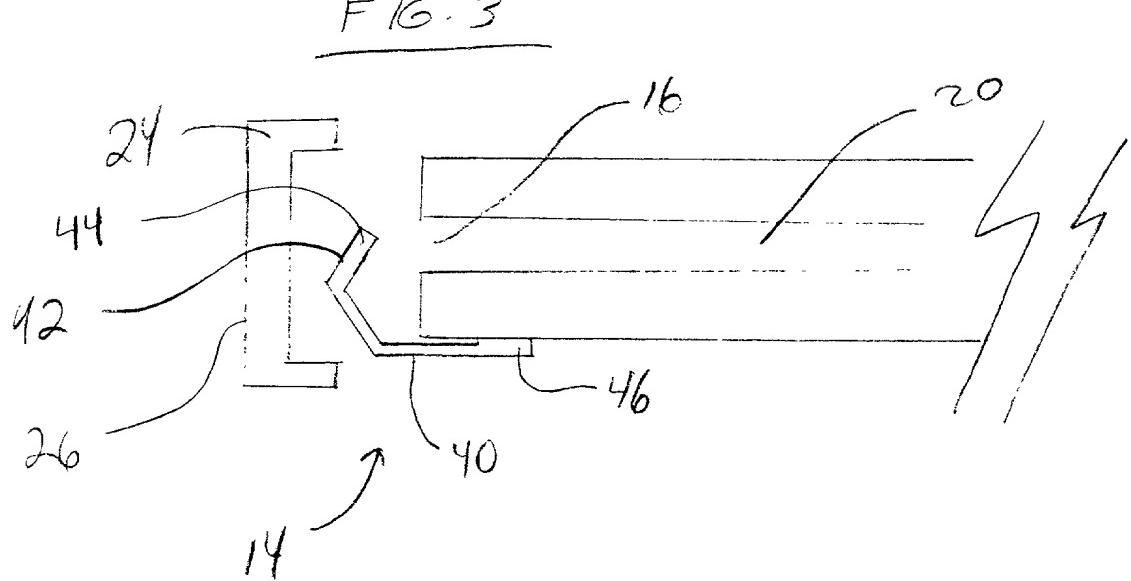
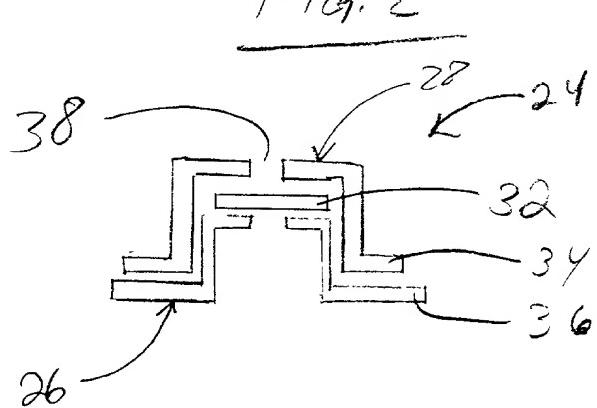
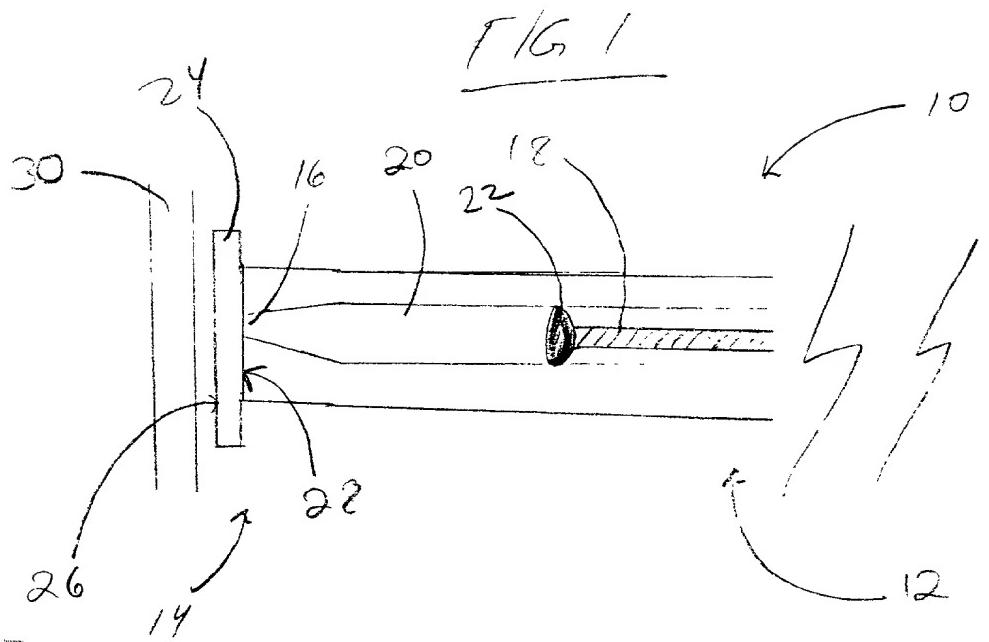
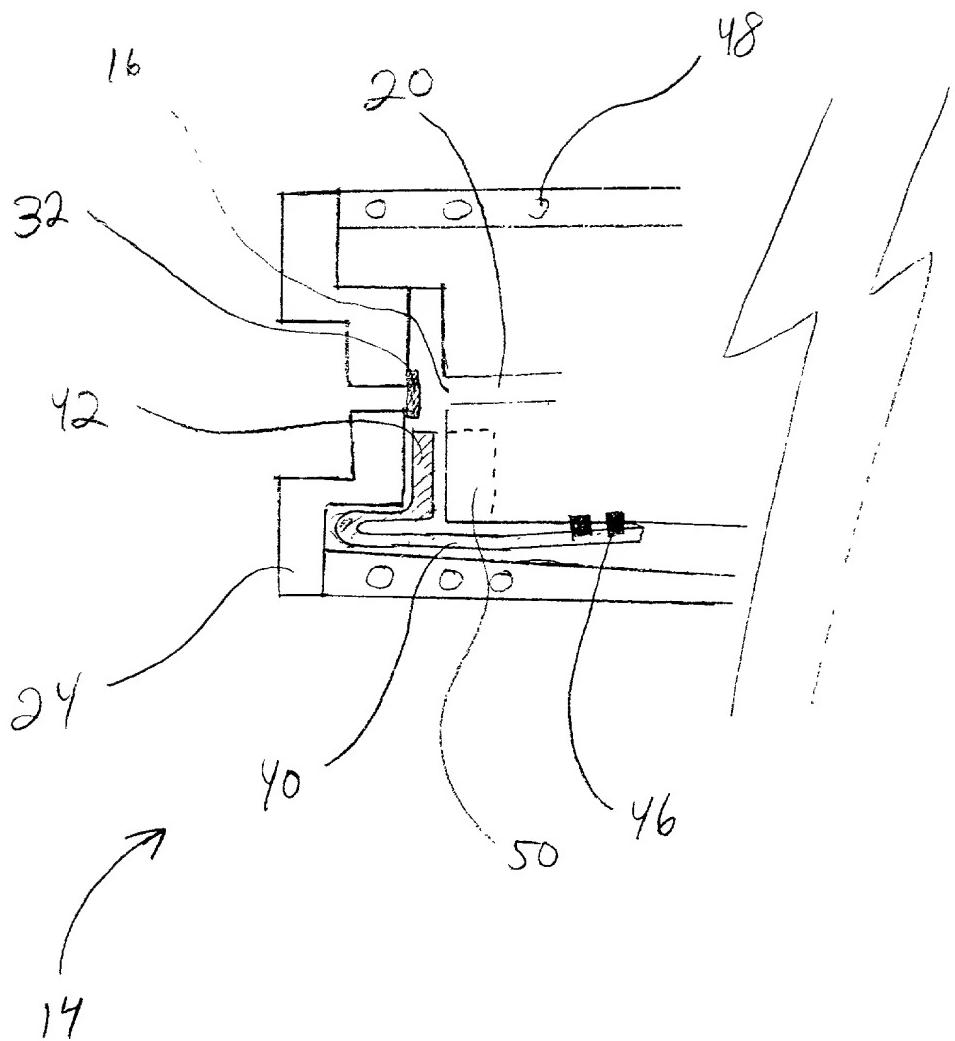
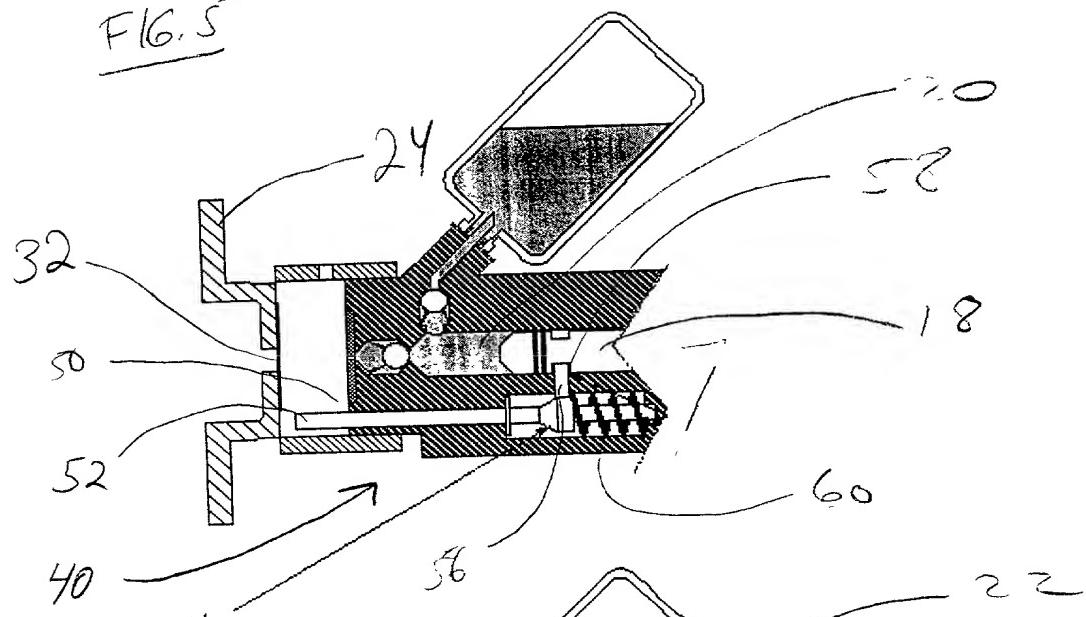


FIG. 1



F16.5



F16.6

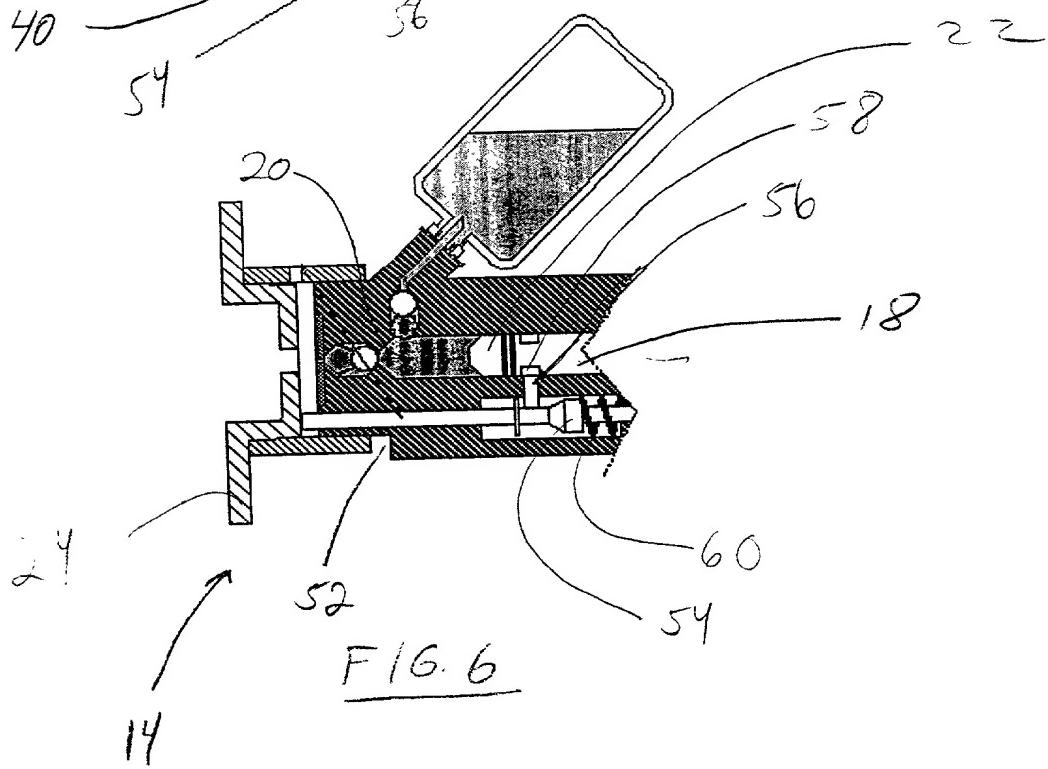


FIG. 7

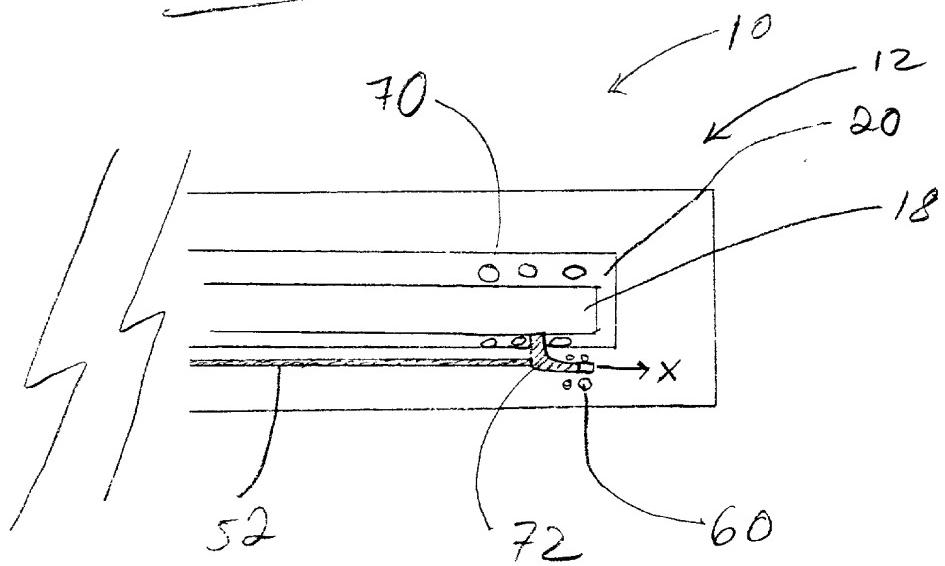


FIG. 2

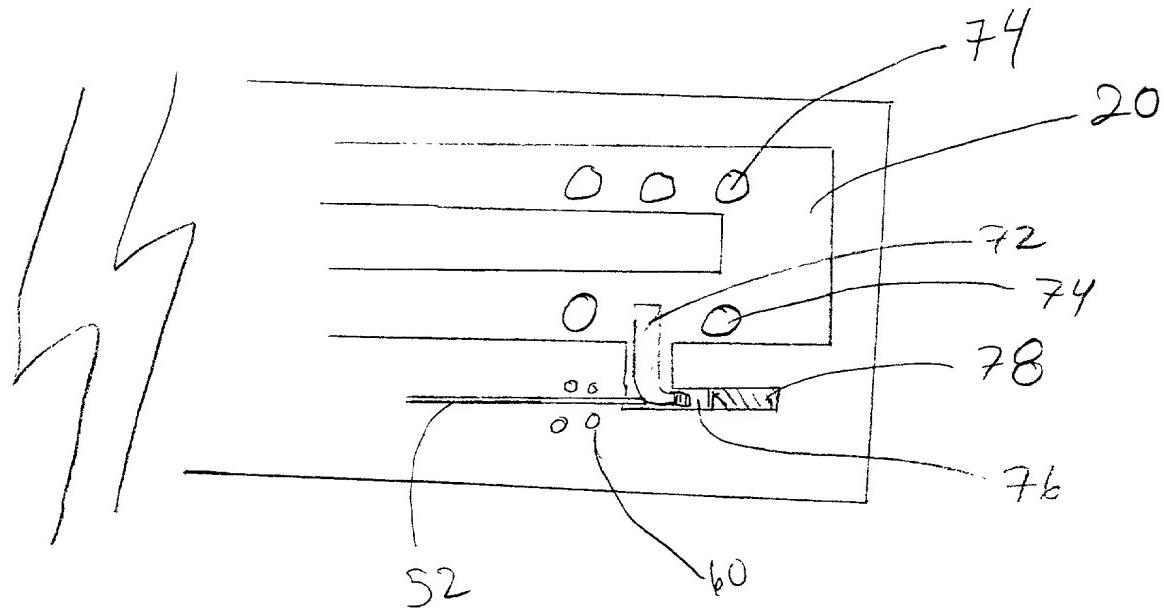


FIG. 9

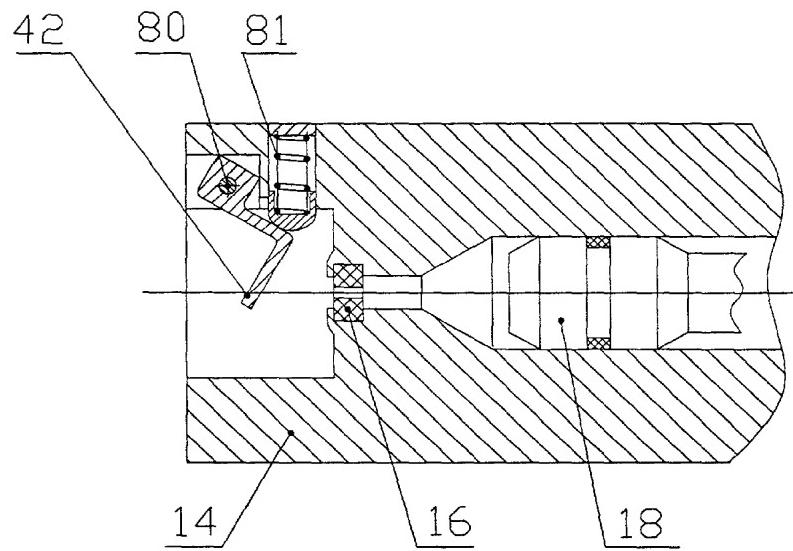
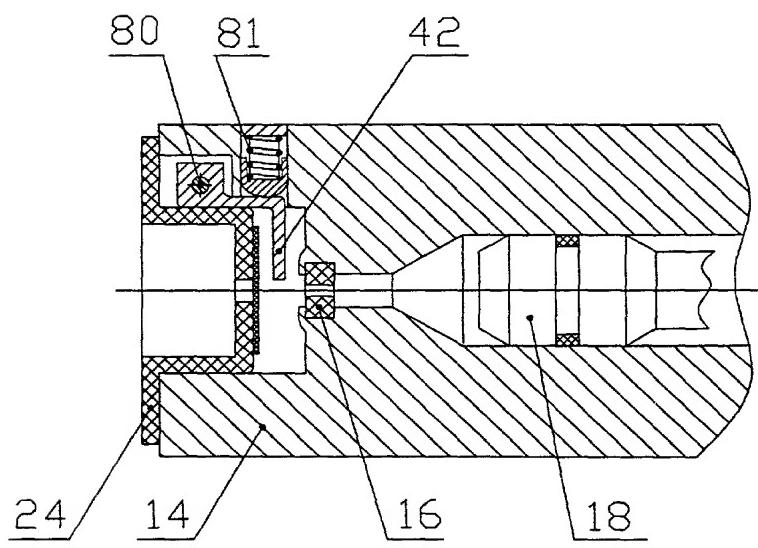


FIG. 10



**PATENT
IN THE UNITED STATES PATENT & TRADEMARK OFFICE**

APPLICANT: B. Smolyarov, et al.

SERIAL NO.: not yet assigned

FILED: November 21, 2000

FOR: SAFETY MECHANISM TO
PREVENT ACCIDENTAL
PATIENT INJECTION AND
METHODS OF SAME

EXAMINER: not yet assigned

CASE NO.: 70006780-0008

GROUP ART UNIT: not yet assigned

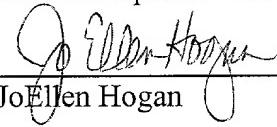
DATE: November 21, 2000

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**DECLARATION AND POWER OF ATTORNEY
FOR A UNITED STATES PATENT APPLICATION**

As a below-named inventor, I hereby declare:

My residence, post office address and citizenship are as stated below next to my name. I believe I am an original and first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled SAFETY MECHANISM TO PREVENT ACCIDENTAL PATIENT INJECTION AND METHODS OF SAME, the specification of which is attached.

I hereby state that I have reviewed and understand the contents of the above-mentioned specification, including the claims.

I acknowledge a duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, 1.56.

Claim to benefit of foreign application(s) as follows:

I hereby claim foreign priority benefits under 35 U.S.C. §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application(s) for patent or inventor's certificate on this invention having a filing date before that of the application on which priority is claimed:

99124268
(Number)

Russia
(Country)

23 Nov. 1999
(DD,MM,YY)

Priority Claimed

Claim to benefit of earlier U.S. application(s) as follows:

I hereby claim the benefit under 35 U.S.C. §120 of the following earlier-filed United States patent applications. Insofar as the subject matter of each of the claims of this application is not disclosed in the prior U.S. applications in the manner required by 35 U.S.C. §112, first paragraph, I acknowledge a duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56 which came into existence between the filing date(s) of the prior applications and the national or PCT filing date of this application.

U.S. Serial No. 09/685,499, filed October 10, 2000
U.S. Serial No. 09/685,633, filed October 10, 2000

I hereby appoint the following Attorneys and/or agents to prosecute this application and any continuation or divisional applications based hereon, and to transact all business in the Patent and Trademark Office connected therewith:

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I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that all statements made herein were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

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Nathaniel Leon Date